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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,706	12/11/2003	James E. Hagstrom	Mirus.048.01	8647

7590 09/13/2005

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,706	HAGSTROM ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/05 has been entered.

Claims 1-9, 12-13 and 15-16 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-9 and 12-13 and 15-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stedman et al (WO 99/31982, 1999) for the same reasons of record as set forth in the office action mailed on 6/2/05.

The instant claims are drawn to a method for delivering polynucleotide to extra vascular parenchymal cell in a limb of a mammal in-vivo by inserting a viral vector in large volume into the lumen of vessel.

Stedman teaches transvascular delivery of a composition comprising a viral vector to an extravascular tissue of a mammal. Regarding claims 1-4 the cited art

teaches the transport of an adenovirus vector from the lumen of vascular capillaries to the interstitium of muscle tissue (page 53 example-1). The cited art teaches that the adenoviral vector (AdCMVlacZ) is delivered into the vessel (artery or vein) by inserting a single injector under pressure into a tissue wherein the flow of blood in the tissue has been occulted from five to forty-five minutes (page 54, lines 13-28, page 55 lines 10-15). Therefore the cited art clearly teaches a range of time that is within optimal range as claimed in the instant application. Regarding claims 5-9 the cited art teaches delivery of a viral vector though an artery or a vein (example -1, pages 54-56). Regarding claim 12 the cited art teaches increasing vessel permeability by providing virus vector suspension continuously at high pressure (20 pounds per seq. inch or 80 pounds per seq. inch) see page 55 lines 1-18. Regarding claims 11 and 16 the cited art further teaches increasing vascular permeability using permeability-enhancing agent is selected from the group consisting of histamine, acetylcholine, an adenosine nucleotide, arachidonic acid, bradykinin, cyanide, endothelin, endotoxin, interleukin-2, ionophore A23 187, nitroprusside, a leukotriene, an oxygen radical, phospholipase, platelet activating factor, protamine, serotonin, tumor necrosis factor, vascular endothelial growth factor, a venom, and a vasoactive amine (page 8, lines 18-28, page 20, page 63 example-2). Regarding claims 13 and 14 the cited art teaches the delivery of viral vector via increasing vascular permeability to muscle cells, cardiac muscle cell and liver cells (page 73 example-5, example-6, fig-4). Regarding claim 15-16 the cited art teaches increasing vessel permeability by providing virus vector suspension continuously at high pressure (20 pounds per seq. inch or 80 pounds per seq. inch) see page 55 lines 1-18). In addition the cited art further teaches increasing vascular permeability by occlusion of hepatic inflow (page 54 lines 21-28) and treatment with histamine prior to infusion of virus vector (page 55, line 25-28). Thus the cited art clearly anticipate the invention as claimed.

Response to Arguments

The applicant argues that the method taught by Stedman requires perfusion of the limb for 45 minutes. The applicant furhtrer argues that prior art perfusion requires at least two vessels therefore instant claims has been amended to recite insertion of a

single injector. The applicant argues that the instant claims has been further amended to recite rapid injection of viral solution and removal of inclusion within two minutes, which differentiates instant claims from the prior art. However, applicant's argumetns are found not persuasive. Given the broadest reasonable interpretation the invention as claimed encompasses delivery of a viral vector to to extravasculear cells via an intravascular administration. Stedman clearly teaches transvascular delivery of a composition comprising a viral vector to an extravascular tissue of a mammal. The cited art teaches the transport of an adenovirus vector from the lumen of vascular capillaries to the interstitium of muscle tissue (page 53 example-1). The cited art teaches delivery of a viral vector though an artery or a vein. The cited art teaches that an adenoviral vector is delivered into the vessel (artery or vein) by inserting a single injector under pressure into a tissue wherein the flow of blood in the tissue has been occulted from five to forty-five minutes (page 54, lines 13-28, page 55 lines 10-15).

It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314.

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added). In instant case the prior art of record clearly teaches the cited art teaches that an adenoviral vector is delivered into the vessel (artery or vein) by inserting a single injector under pressure into a tissue wherein the flow of blood in the tissue has been occulted from five to forty-five minutes. Therefore as claimed in the instant application releasing occlusion within about two minutes after injection is considered routine optimization. Thus the cited art clearly anticipate the invention as claimed.

Conclusion

No claims are allowed.

This is a RCE of applicant's earlier Application No. 10733706. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547.** For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300.**

-sk

SUMESH KAUSHAL
PATENT EXAMINER